years, while low risk patients exceeded it in 15 years, respectively. Coexisting risk resulted in a sharp increase in the incidence of CRC exceeding the benchmark risk in less than 3 years. **CONCLUSIONS:** Intervals based on incidence of CRC diverge from adenoma only surveillance recommendations and suggest a longer interval of follow-up except for those with co-existing risk.

MEDICAL DEVICE/DIAGNOSTICS - Cost Studies

PMD13

BUDGET IMPACT MODEL OF A BLOOD BASED PROTEOMIC CLASSIFIER FOR INDETERMINATE PULMONARY NODULES

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OBJECTIVES: Depending on the penetration of screening recommendations, it is possible that the incidence of detected pulmonary nodules (PNs) could increase exponentially in coming years. Currently PN evaluation routinely requires costly procedures including imaging, biopsy and surgery. A molecular blood based test that measures plasma proteins using selected reaction monitoring mass spectroscopy allows for an objective and quantitative assessment of PN benignity. This budget impact analysis was performed to quantify the molecular test impact on a US commercial health plan's direct medical costs. **METHODS:** The budget impact model was developed from a commercial health plan perspective, with direct medical costs estimated from the MarketScan® reimbursement benchmark data. Total PN diagnostic evaluation costs were estimated for a 2-year time horizon and were calculated for the current standard of care and care with the introduction of the molecular test. Diagnostic procedure resource utilization was obtained from a retrospective chart review analysis of a geographically representative sample of indeterminate PNs (8-20mm) managed by outpatient pulmonologists. **RESULTS:** Currently, 52% of PNs are evaluated with an invasive procedure (biopsy/surgery) and 48% with surveillance alone, with significant cost differences observed between these two groups. The base case analysis using a health plan of one million members and a rate of 0.25% PNs within the health plan, estimated a 27% reduction in avoidable invasive procedures with the introduction of the molecular test. This amounted to a total potential cost savings of 20% from procedure and complication avoidance. **CONCLUSIONS:** Adoption of this molecular test may help reduce the number of unnecessary invasive procedures being performed for individuals presenting with indeterminate pulmonary nodules. The reduced resource utilization can result in cost savings for the health plan.

PMD14

AN ECONOMIC MODEL OF THE IMPACT OF DIGITAL MEDICINES WITH A MOBILE APPLICATION IN PATIENTS WITH COMORBID HYPERTENSION, DIABETES, AND HYPERCHOLESTEROLEMIA

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OBJECTIVES: There is a strong correlation between cardiovascular disease and diabetes with management of blood pressure (BP), blood glucose (BG), and lipids being essential to preventing disease progression and complications. The FDA-cleared Proteus device captures and shares information about medication-taking, rest and activity patterns through a mobile device and app, a patch with a wearable sensor inside, and sensor-enabled pills. This offering facilitates patient engagement and behavioral change, informative provider decision-making, and improvement of outcomes. An economic model was developed to estimate the impact of reducing BP, BG, and lipids via the Proteus offering. **METHODS:** The value of 1-month use of the Proteus offering to reduce BP, BG, and lipids was evaluated in patients with comorbid hypertension, type 2 diabetes, and hypercholesterolemia from a US payer perspective for a 1-year time horizon. The clinical and utilization assumptions were derived from the literature, expert opinion, and a real-world Proteus study in patients with uncontrolled hypertension. Costs were derived from the Medicare Fee Schedule and AHRQ databases. Payers were also interviewed for current management of these conditions as input to the model. **RESULTS:** The cost offsets of the Proteus service offering were estimated to be $90-185 per month of use, including current reimbursement for medications and medication adherence solutions. Medical cost savings consisting of reductions in outpatient and inpatient services, monitoring, disease management, and medication costs were estimated to be $850-980 per patient per year (PPPY), which was mainly driven by a 5-11% reduction in diabetes and CVD complications. Revenue opportunities via meeting quality measures presented an additional value equating to $80-95 PPPY, bringing the total value of the Proteus offering to $1020-1260 PPPY. **CONCLUSIONS:** The Proteus offering provides opportunities to mitigate the high costs of managing at-risk patients with multiple cardiometabolic comorbidities.

PMD15

MEDICARE BENEFICIARY OUT-OF-POCKET SPENDING FOR STROKE PREVENTION IN NON-VALVULAR ATRIAL FIBRILLATION: A BUDGET ANALYSIS

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OBJECTIVES: Healthcare costs today are increasingly being shifted from payers to patients, yet few providers factor patient costs into treatment decisions. Recent advancements in stroke prevention in atrial fibrillation (AF) have resulted in new treatment options where previously there were few. While the clinical benefit and cost effectiveness of these treatments are supported by a growing body of evidence, the cost impact to patients has not been explored. This analysis sought to quantify patient out-of-pocket costs for three stroke prevention strategies: warfarin, dabigatran and left atrial appendage closure (LAAC) with the Watchman Device. **METHODS:** A patient-level budget impact model was used to assess total out-of-pocket spend on treatment and treatment-related complications over five years. 2015 Medicare deductibles and co-insurance rates were used to estimate spend for LAAC, acute clinical events and office visits. Average drug costs were calculated from the four states with the largest number of Medicare beneficiaries. Patient stay days were taken from HCUP and inpatient rehabilitation prospective payment system data. Clinical probabilities for LAAC and warfarin were taken from PROTECT AF 4-year data and for dabigatran from the RE-LY trial. **RESULTS:** The deductible for the LAAC procedure was $1,260. This compares to an average annual acquisition cost of roughly $345 for warfarin and $1,048 for dabigatran. First year total costs were $1,734, $1,023 and $1,335, for LAAC, warfarin and dabigatran, respectively. By the end of year 2, LAAC was less expensive with total costs of $2,353 compared to $2,702 (warfarin) and $2,865 (dabigatran). By year 5, LAAC was approximately half the cost of anticoagulants. **CONCLUSIONS:** Patient out-of-pocket costs for stroke prevention in AF are considerable and may represent a burden for many Medicare beneficiaries living on fixed incomes. LAAC with the Watchman Device provides lifetime stroke prophylaxis without increased bleeding risk at a lower cost to patients.

PMD16

ECONOMIC ANALYSIS OF EVARRESTTM COMPARED WITH STANDARD CARE IN CHALLENGING LIVER SURGICAL BLEEDING POPULATIONS: A U.S. HOSPITAL PERSPECTIVE

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OBJECTIVES: Bleeding in liver surgery can be difficult to control due to extreme vascularity and tissue fragility, including compromised liver (e.g., cancer). Blood loss may be minimized with hemostats that have rapid effect and may impact cost of care. This study estimated budget impact of using EVARREST vs. SoC in hepatic surgery based on two randomized trials. **METHODS:** An economic analysis was developed to quantify 30-day cost impact of EVARREST from a U.S. hospital perspective. Key resources, from two randomized trials (n=180), included initial treatment, retreatment, operating time, transfusions, ventilator, and hospitalization. Transplant patients (n=6) where normal liver tissue was resected were excluded from analyses. SOC was composed mainly of manual compression alone or with hemostats. The surgical analysis included resources clinically related to significant hemostasis benefits of EVARREST (i.e. retreatment, operating time, transfusion). A hospital analysis included all resources collected. Economic analyses were completed for the following subgroups: abnormal liver, metastatic cancer, anatomic/non-anatomic liver (classifications using IHPBA definitions), cirrhotic/steatotic liver, and if patients were obese or coagulopathic. Published U.S. costs were applied to resource use. Analysis results were weighted based on trial size. **RESULTS:** The surgical analysis predicted that the EVARREST cost was offset vs. SoC with a trial-weighted cost impact of $719 per patient. The hospital analysis predicted further resource reduction with EVARREST with trial-weighted cost-savings of $868 per patient. Subgroup analyses demonstrated a range of results from cost impact to cost savings with EVARREST vs. SOC (i.e., $1,976 to -$5,430 per patient, hospital analysis). EVARREST use in coagulopathic patients was found to have the largest degree of cost savings with $1,859 and $5,176 per patient anticipated, surgical and hospital results respectively. **CONCLUSIONS:** In addition to meeting an important unmet need in controlling problematic bleeding in liver tissue, this analysis suggests that EVARREST can be a cost saving strategy.

PMD17

CLINICAL AND BUDGET IMPACT OF USING A TEST TO DETECT KRAS MUTATIONS IN METASTATIC COLORECTAL CANCER PATIENTS IN THE UNITED STATES

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OBJECTIVES: Anti-epidermal growth factor receptor (EGFR) therapies are ineffective in tumors with KRAS mutations in exon 2 codons 12 and 13. Thus, guidelines have recommended determination of KRAS mutation status in metastatic colorectal cancer (mCRC). Both the **cobas®** KRAS Mutation Test (cobas® test, currently available as Research Use Only in the US) and the therascreen KRAS RGQ PCR Kit (therascreen test) detect KRAS mutations in exon 2; cobas® test detects twelve mutations and therascreen test detects seven mutations in exon 2. We estimated the potential clinical and budgetary impact of using the cobas® test versus therascreen test in the mCRC setting. **METHODS:** A budget impact model comparing the clinical and economic outcomes of using the cobas® test versus therascreen test was developed from the US payer perspective. We assumed 42,000 annual cases of mCRC patients. Model inputs were obtained from literature, whereas testing and treatment costs were calculated from CMS reimbursement rates. KRAS test sensitivity reflected the test's ability to detect mutations in codons 12 and 13; specificity was assumed to be the same for both tests. The model calculated the average cost for mCRC patients over 5 years, using median time on treatment and median overall survival. Based on current practice patterns, the proportion of patients receiving KRAS testing before 1st-line, 2nd-line, and 3rd-line therapy were 42%, 32%, and 26%, respectively. **RESULTS:** Adopting the cobas® test resulted in a reduction of 289 patient-months lost due to non-optimal care (i.e. by avoiding anti-EGFR therapies in mutant positive patients) and an improvement in median overall survival. Adopting the cobas® test generated a total of $2.3 million in cost savings and an average decrease of $7 per mCRC patient per month. **CONCLUSIONS:** Using the cobas® test with improved sensitivity was associated with a reduction of patient-month lost and a decrease of healthcare costs in mCRC patients.

PMD18

THE USE OF ULTRASONIC ENERGY IN MASTECTOMY AND LUMPECTOMY PROCEDURES: A BUDGET IMPACT ANALYSIS

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